

Dosing Information: New Formulation of Carbinoxamine/Pseudoephedrine Drops

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BACKGROUND - Carbinoxamine/Pseudoephedrine (Rondec®) drops have recently been re-formulated. A generic product is available for the new formulation. The previous formulations are being withdrawn from the market.

Old formulation	New formulation
2 mg carbinoxamine and 25 mg pseudoephedrine per 1 mL	1 mg carbinoxamine and 15 mg pseudoephedrine per 1 mL

The BCF listing was clarified at the May 2002 DoD P&T committee meeting to specify carbinoxamine 1mg/mL and pseudoephedrine 15mg/mL oral drops. The specification "Rondec or equivalent" was removed.

THE PROBLEM - The formulation was reportedly changed due to concerns about potential overdosing of pseudoephedrine if the product is dosed by weight based on the carbinoxamine component. The new formulation decreases the concentrations of both components, but actually increases the carbinoxamine:pseudoephedrine ratio. If providers fail to note the differences in drug concentrations and continue to dose the product based on the previously recommended daily dose of carbinoxamine (0.2-0.4 mg/kg/day), the likelihood of excessive administration of pseudoephedrine increases. Unfortunately, instructions in the new package labeling are based on age only, and provide no guidance about appropriate dosing of either component by weight.

RECOMMENDATION - Dose carbinoxamine and pseudoephedrine 1 mg/15 mg per mL drops based on the pseudoephedrine component. Maintain the pseudoephedrine dose at 4 mg/kg/day or below to minimize the risk of side effects and toxicity. Both pseudoephedrine and its active metabolite are excreted renally: adjust doses in patients with decreased renal function.

DOSING TABLES

Dosing of NEW formulation carbinoxamine/pseudoephedrine drops (1 mg:15 mg / mL = 1 dropper) based on pseudoephedrine component

Weight	Dose	Carbinoxamine	Pseudoephedrine (4 mg/kg/day)
5 kg	1/3 dropper QID	0.27 mg/kg/day	4 mg/kg/day
10 kg	2/3 dropper QID		
15 kg	1 dropper QID		

Dosing of NEW formulation carbinoxamine/pseudoephedrine drops (1 mg:15 mg / mL = 1 dropper) based on package labeling

Age	Dose	Carbinoxamine	Pseudoephedrine
1 - 3 months	¼ dropper QID	0.25 mg	3.75 mg
3 - 6 months	½ dropper QID	0.5 mg	7.5 mg
6 - 12 months	¾ dropper QID	0.75 mg	11.25 mg
12 - 24 months	1 dropper QID	1 mg	15 mg